

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

v.

(1) STRYKER BIOTECH, LLC,

(2) MARK PHILIP,

(3) WILLIAM HEPPNER,

(4) DAVID ARD and

(5) JEFFREY WHITAKER,

Defendants.

Criminal No.: 09-CR-10330-GAO

**GOVERNMENT’S CONSOLIDATED MEMORANDUM IN OPPOSITION TO
DEFENDANTS’ MOTIONS TO SEVER COUNTS**

The government hereby submits its consolidated memorandum in opposition to the separate motions filed by (1) William Heppner, David Ard, and Jeffrey Whitaker; (2) Stryker Biotech; and (3) Mark Philip (collectively, “Defendants”) to sever Count 15 of the Indictment.¹ Under either Federal Rule of Criminal Procedure 8(b) or 14, the Court should deny Defendants’ motions because Count 15 is properly joined and any minimal prejudice arising from Count 15 can be cured with limiting instructions.

BACKGROUND

On October 29, 2009, a grand jury returned the Indictment against Defendants. Counts 1-14 deal with acts of wire fraud, misbranding, and related conspiracies that supported off-label promotion of an unapproved OP-1 and Calstrux mixture. Count 15 deals with Stryker Biotech submitting a false

¹ In addition to filing their own motions, Stryker Biotech and Philip each joined in Heppner, Ard, and Whitaker’s motion. Philip also joined in Stryker Biotech’s motion.

statement in an annual report to the FDA that served to conceal the results of the off-label promotion embodied in Counts 1-14.

Counts 1-5 allege that Defendants committed wire fraud; Count 6 alleges that Defendants conspired both to defraud the FDA and to commit misbranding; and Counts 7-14 allege that Stryker Biotech, Ard, or Whitaker distributed a misbranded device. The government alleges that each of these crimes arises from the illegal promotion of a mixture of two products, OP-1 and Calstrux, that were not FDA approved as a combined or mixed product.

OP-1—both in its Implant and Putty forms—was approved by the FDA under a Humanitarian Device Exemption (“HDE”) which is only available for devices designed to treat conditions that affect fewer than 4,000 individuals in the United States. 21 U.S.C. §360j(m); (Indictment (“Indict.”) at ¶¶12(D)(1), 17, and 18)). Because of that, Stryker Biotech was obligated to submit annual reports to the FDA reporting the number of OP-1 devices shipped or sold. (Id. at ¶71.) If Stryker Biotech shipped or sold more than 4,000 units of either OP-1 product in a given year, the company had to explain (if it could) why that excess number did not represent excess sales. Id.; 21 C.F.R. §814.126. Exceeding the patient limit could have resulted in the FDA revoking OP-1's HDE status and taking the device off the market. (Id. at ¶75 (knew of significant risks if patient limit exceeded)).

Count 15 alleges that Stryker Biotech made a false statement to the FDA when it submitted its annual report for OP-1 Putty on or about April 30, 2007.² In that annual report, Stryker Biotech reported it had sold 6,234 units, claimed that “2 units of OP-1 Putty are used per patient,” and

² Count 16, a false statement charge against Philip concerning the April 2008 annual report, was dismissed upon an assented-to motion filed by the government.

estimated that 3,117 patients received the product. (Id. at ¶¶78). If 2 units were used per patient, the company could theoretically sell 8,000 units. In reality, however, the company knew that approximately 1.3 units were used per patient and that more than 4,000 patients ($6,234/1.3 = 4,795$) received OP-1 Putty during the relevant reporting period. (Id. at ¶¶75 and 78). The increased patient number was a natural consequence of Defendants' ongoing illegal promotion, and Stryker Biotech's false statement cloaked that on-going illegal promotion from the FDA.

ARGUMENT

A. COUNT 15 IS PROPERLY JOINED UNDER RULE 8(b)

Rule 8 of the Federal Rules of Criminal Procedure governs joinder, and the First Circuit has determined that Rule 8(b) governs joinder of defendants and offenses in cases, such as this one, that involve multiple defendants.³ United States v. Natanel, 938 F.2d 302, 306-7 (1st Cir. 1991). Rule 8(b) states:

The indictment or information may charge 2 or more defendants if they are alleged to have participated in the same act or transaction, or in the same series of acts or transactions, constituting an offense or offenses. The defendants may be charged in one or more counts together or separately. All defendants need not be charged in each count.

Under this rule, the government may charge and join parties, “on the basis of what it reasonably anticipates being able to prove against the defendants, collectively, measured as of the

³ Stryker Biotech moves to sever pursuant to Rule 8(a), but that rule (admittedly more favorable to the government) applies only to joinder of offenses in a case against a single defendant. United States v. Natanel, 938 F.2d 302, 306-7 (1st Cir. 1991) (“*In a case involving multiple defendants*, Rule 8(b) governs joinder of defendants *and* offenses”) (emphasis added); see also King v. United States, 355 F.2d 700, 704 (1st Cir. 1966) (“Rule 8(b) is not to be implemented by Rule 8(a)[]”). The government does not need to satisfy both Rule 8(a) and 8(b) to justify its joinder of Count 15; there is not one standard for Stryker Biotech and another for the remaining defendants.

time the indictment is handed up.” Natanel, 938 F.2d at 306. While a rational basis for joinder must be discernable from the face of the indictment, explicit cross-references between counts are not required. Id. at 306-7. This “rational” basis has also been described as a “plausible” basis. United States v. Fenton, 367 F.3d 14, 15 (1st Cir. 2004). Each defendant need not be involved in each offense charged, as “joinder is proper so long as there is some common activity binding the objecting defendant with all the other indictees and that common activity encompasses all the charged offenses.” Natanel, 938 F.2d at 307. Defendants bear the burden of persuading the court that joinder is improper. Id. at 306. Under Rule 8, severance is the remedy for misjoinder. Id.

Joinder of offenses under Rule 8(b) has been upheld when, for example, the offenses (1) are linked by a conspiracy charge, or (2) share common facts or are supported by common evidence. United States v. Trainor, 477 F.3d 24, 32 (1st Cir. 2007); United States v. Doherty, 867 F.2d 47, 53 (1st Cir. 1989) (citing United States v. Arruda, 715 F.2d 671, 678 (1st Cir. 1983)). Under either of these scenarios, Count 15 is properly joined.

1. Charged Conspiracies Support Joinder of Count 15

A conspiracy count can serve as the link required to join multiple counts. “[I]t is axiomatic that a defendant can be charged with both the conspiracy and the substantive offenses arising from it.” United States v. Yefsky, 994 F.2d 885, 895 (1st Cir. 1993) (affirming denial of Rule 8(b) motion, noting that charged conspiracy “embraced many of the acts that constituted the [underlying substantive counts]”); see also Trainor, 477 F.3d at 32 n.15 (claim of improper joinder unavailing when “all of the alleged acts of wire fraud were within that conspiracy and thus necessarily a part of the same case”); Natanel, 938 F.2d at 307 (“[I]t is settled that a conspiracy count can forge the

needed linkage.”). In Count 6, Defendants are charged with two conspiracies: (1) conspiring to defraud the FDA; and (2) conspiring to promote off-label mixtures of OP-1 and Calstrux. Counts 1-5 and 7-14 all charge overt acts that furthered Count 6; Count 15 also charges an overt act done by a co-conspirator in furtherance of Count 6. “[C]oncealment in order to achieve the central purpose of [a] conspiracy” can be part of that conspiracy. United States v. Upton, 559 F.3d 3, 23 (1st Cir. 2009), citing Grunewald v. United States, 353 U.S. 391, 413 (1957) (distinguishing between concealment of completed conspiracies and acts of concealment done to achieve central purpose of conspiracy). The filing of the false statement in the April 2007 annual report concealed the consequences of both the conspiracy to defraud the FDA and the conspiracy to misbrand OP-1, thus allowing the conspiracies to continue.

Defendants argue that the conspiracy charge fails to establish joinder because Count 6 does not *explicitly* reference the facts underlying Count 15 as overt acts in furtherance of the conspiracy. (September 13, 2011 Heppner, Ard, and Whitaker Memorandum In Support of Severance (“Heppner Memo.”) at 6; September 14, 2011 Stryker Biotech Memorandum in Support of Severance (“Stryker Memo.”) at 4). Defendants cite no authority to support of their proposition. Indeed, the First Circuit has, in analogous circumstances, held that indictments need not explicitly cross-reference linked charges. Natanel, 938 F.2d at 307 (explicit cross-reference between charges not required even where they would have made connections “more easily visualized”). Natanel dealt with a continuing criminal enterprise (“CCE”) count that was a sufficient link between multiple defendants and offenses; joinder was justified because the “CCE tie[d] in the remaining counts of the indictment.” Id. Here, Count 6 serves as that sufficient link.

The Indictment does what is required. It provides a rational, or plausible, basis for the joinder of Count 15 that is discernable from the face of the Indictment. While Counts 1-14 allege some form of illegal promotion of OP-1 mixed with Calstrux, Count 15 alleges the false statement that concealed those activities from the FDA. After all, if Stryker Biotech had accurately reported the more than 4,000 patients, it would have raised a “red flag” concerning potential illegal promotion, risked the withdrawal of OP-1 Putty, and endangered the objective of Defendants’ conspiracies. That linkage is readily discernable from the face of the indictment.

2. Common Facts and Evidence Support Joinder of Count 15

Defendants also argue that joinder is improper because the evidence needed to prove Count 15 “does not overlap” with the evidence needed to prove Counts 1-14. (Stryker Memo. at 4). That is wrong. First, the government anticipates that virtually all of its Count 15 witnesses will also offer testimony related to some subset of Counts 1-14.⁴ Second, both the falsity and materiality of Stryker Biotech’s statement to the FDA are directly tied to the promotion, sales, and use of OP-1 Putty– and the alleged illegal promotion of that product with Calstrux is at the core of the government’s evidence for Counts 1-14. Third, specifically called out in Count 6 or not, the acts underlying Count 15 are overt acts by a co-conspirator in furtherance of Count 6 that would be separately admissible against *all Defendants*. Defendants’ assertion that the evidence will not overlap is without foundation.

In part because of these overlapping witnesses and facts, judicial efficiency argues on behalf

⁴ Ms. Supko, referred to by Defendants, is perhaps the sole exception. (Stryker Memo.at 5).

of trying Count 15 with Counts 1-14. Defendants attempt to be on both sides of the judicial efficiency argument by implying both that a subsequent case would be short and that inclusion of Count 15 in this case would cause the trial to be unduly long. (Id. at 2, 4, 5, and 8). As argued above, the length of the present trial will not be significantly increased by inclusion of Count 15 because of witness overlap and evidentiary overlap. That same overlap, however, means that at a second trial the government would have to recapitulate, at length, a number of the same witnesses and evidence. Severance would result in judicial, prosecutorial, and witness inefficiency.⁵

For all these reasons, the government requests that the Court deny Defendants' various motions to dismiss pursuant to Rule 8(b).

B. DEFENDANTS HAVE FAILED TO MAKE THE STRONG SHOWING OF PREJUDICE NECESSARY TO JUSTIFY SEVERANCE PURSUANT TO RULE 14

Although Count 15 is properly joined, Rule 14 of the Federal Rules of Criminal Procedure provides Defendants another opportunity to seek severance. Rule 14 allows for severance:

[i]f the joinder of offenses or defendants in an indictment, an information, or a consolidation for trial appears to prejudice a defendant or the government, the court may order separate trials of counts, sever the defendants' trials, or provide any other relief that justice requires.

⁵ In its memorandum, Stryker Biotech: (1) volunteers the government for a bench trial on Count 15; (2) refers to (unidentified) possible stipulations that would allegedly shorten a subsequent trial; (3) implies that the government would forego Count 15 should it not convict on the remaining counts; and (4) further implies that Stryker Biotech would resolve Count 15 short of trial should the company lose on the remaining counts. (Stryker Memo. at 2, and 8-9). The government notes that it has not waived a jury trial, has not received proposed stipulations from Defendants, and that speculation as to what any party would do in the event of a severance is baseless.

Because the counts are properly joined, the Court should grant severance, "only if there is a serious risk that a joint trial would compromise a specific trial right of one of the defendants, or prevent the jury from making a reliable judgment about guilt or innocence." Zafiro v. United States, 506 U.S. 534, 539 (1993). There is a strong policy preference for jointly trying defendants charged in related crimes. Id. at 537. Defendants bear the burden of making a strong and convincing showing of prejudice. United States v. Richardson, 515 F.3d 74, 83 (1st Cir. 2008) (citations omitted). Indeed, to justify severance, Defendants must prove "prejudice so pervasive that a miscarriage of justice looms." United States v. Bucci, 525 F.3d 116., 127 (1st Cir. 2008) (citations omitted); United States v. Sotomayor-Vasquez, 249 F.3d 1, 17 (1st Cir. 2001) (citation omitted). Moreover, co-conspirators like Defendants are traditionally tried together absent a strong showing of prejudice. United States v. Fernandez-Hernandez, – F.3d –, 2011 WL 2567893, *13 (1st Cir. June 30, 2011) (quoting United States v. Perkins, 926 F.2d 1271, 1280 (1st Cir. 1991)); Bucci, 525 F.3d at 127. Prejudice must be strong and convincing because, "[s]ome prejudice results in almost every trial in which the court tries more than one offense together." Richardson, 515 F.3d at 81 (citation omitted); see also, e.g., Natanel, 938 F.2d at 308 ("Under the best of circumstances, this is a difficult battle for a defendant to win[]"); United States v. DeLuca, 137 F.3d 24, 36-37 (1st Cir. 1998) ("[A] measure of evidentiary spillover is a foreseeable concomitant of virtually every joint trial, yet seldom indicates undue prejudice"). Incidental spillover will not suffice. Yefsky, 994 F.2d at 896. Nor will "garden variety" prejudice. United States v. Burgos, 254 F.3d 8, 13-14 (1st Cir. 2001).

There are three types of prejudice to a defendant that may result from trying multiple counts together at a joint trial:

(1) the defendant may become embarrassed or confounded in presenting separate defenses; (2) proof that defendant is guilty of one offense may be used to convict him of a second offense, even though such proof would be inadmissible in a second trial for the second offense; and (3) a defendant may wish to testify in his own behalf on one of the offenses but not another, forcing him to choose the unwanted alternative of testifying as to both or testifying as to neither.

Richardson, 515 F.3d at 81 (quoting United States v. Jordan, 112 F.3d 14, 16 (1st Cir. 1997)). As addressed in detail below, Defendants fail to make a strong showing on any of these bases, and can establish neither that specific trial right is compromised nor that the jury will be prevented from making a reliable judgment. In any event, the Court can manage whatever minimal possibility exists for undue prejudice through the judicious provision of limiting instructions. See Natanel, 938 F.2d at 308 (“we also note approvingly that the court below minimized any possible prejudice by repeatedly instructing the jury to treat the defendants as individuals and to consider each charge separately”).

1. Heppner, Whitaker, and Ard Fail to Make A Strong Showing of Prejudice as to Count 15

Heppner, Whitaker, and Ard (“Sales Defendants”) provide several reasons why they believe that Count 15's inclusion would keep the jury from making a reliable judgment, but their reasons are slight, not strong, and are not improved by bundling. First, Sales Defendants argue that Count 15's evidence would be inadmissible against them in a separate trial. (Heppner Memo. at 10). That is neither a bar to joinder nor accurate. Bucci, 525 F.3d at 127 (preference for trying co-conspirators together “despite reality” that evidence against one defendant often inadmissible against another). As argued above, Count 15 constitutes an overt act by a co-conspirator in furtherance of Count 6. Most of the evidence related to Count 15 would be admissible against *all* Defendants.

Second, Sales Defendants claim that unduly prejudicial “spillover” will result from the jury being unable to compartmentalize the evidence introduced as to Stryker Biotech alone in relation to Count 15. (Heppner Memo. at 10-11). The government takes neither so dim a view of the jurors’ capabilities nor of the Court’s capacity to timely and judiciously provide appropriate limiting instructions. Natanel, 938 F.2d at 308; United States v. Mubayyid, 2011 WL 3849749, *31 (1st Cir. Sept. 1, 2011) (use of instructions “safeguard[ed] against the possibility of prejudicial spillover [...] cautionary instructions weaken[ed] the inference of prejudice to be drawn from any evidence that would not have been independently admissible”). To the extent that any evidence submitted in support of Count 15 is not equally admissible against Sales Defendants in the context of Count 6, the Court can issue appropriate limiting instructions.

Third, Sales Defendants state that, “if a joint trial were permitted [they] would need to explain to the jury how they were not involved in Count 15.” (Heppner Memo. at 11). At first, this argument appears to implicate two potential forms of prejudice: (1) embarrassment or confusion in presenting separate defenses; and (2) forcing Sales Defendants to choose between testifying as to all counts raised at trial or testifying as to none. Richardson, 515 F.3d at 81. In truth it implicates neither. Sales Defendants make no proffer as to how their own defenses would be embarrassed or confused at trial by the inclusion of Count 15 against Stryker Biotech. If they mean to imply that they would present evidence, or conduct cross-examinations, in a way which would be antagonistic to Stryker Biotech, “antagonistic defenses do not *per se* require severance, even if the defendants are hostile or attempt to cast the blame on each other.” Arruda, 715 F.2d at 679. Antagonism of defenses leads to severance, not where there is “fingerpointing and tattling,” but where “the defenses

are so inconsistent that the jury would have to believe one defendant at the expense of the other; the conflict alone establishes the guilt of the defendant.” *Id.* Here, Sales Defendants offer no argument that they would present an antagonistic defense, let alone one that would necessarily establish the guilt of Stryker Biotech.

In a round-about way, Sales Defendants might be implying that they wish to testify as to Count 15, but believe they cannot do so without exposing themselves to cross-examination on other counts about which they do not wish to testify. If so, Sales Defendants must make a “convincing showing” that they have “important testimony to give concerning [Count 15] and a strong need to refrain from testifying on [the other counts].” *United States v. Jordan*, 112 F.3d 14, 17 (1st Cir. 1997). Moreover, Sales Defendants must do so in a timely enough fashion to allow the Court to weigh judicial economy versus their freedom to testify as to any particular charge. *Id.* Sales Defendants have made no showing at all.

For the reasons stated above, Sales Defendants have failed to make a strong and convincing showing either that there is a “serious risk” that jurors will be prevented from making a reliable judgment as to Sales Defendants, or that specific trial rights will be compromised, if Count 15 remains in the case. Accordingly, the government requests that the Court deny Sales Defendants’ Rule 14 motion to sever.⁶

2. Philip Fails To Make A Strong Showing of Prejudice as to Count 15

Philip bases his prejudice arguments on the likelihood that the government will “attempt to

⁶ Stryker Biotech joined Sales Defendants’ motion to sever pursuant to Rule 14, but has offered no reasons why it would be prejudiced by the inclusion of Count 15.

include [Philip] in its proof of Count 15 ... so that it can satisfy the collective knowledge [requirement.]” (September 14, 2011 Philip Motion to Sever (“Phillip Mot.”) at ¶9). He argues variously that: (1) this would be “unfair”; (2) the jury might “blame” him for Count 15 due to his former position as Stryker Biotech’s president; and (3) he “would be forced to challenge the government’s proof” concerning Count 15 “even though he himself is not named in Count 15.” (Id. at ¶¶10, 11, and 12). As with the Sales Defendants, each of Philip’s proffered reasons falls short of the required “strong showing” of prejudice.

Philip claims that inclusion of Count 15 “would be particularly unfair” because the government dismissed Count 16 after receiving “evidence of Philip’s actual innocence as to Count 16.” (Id. at ¶10). That is not so. First, Philip mischaracterizes the government’s reasons for filing an assented-to motion for the dismissal of Count 16. Second, Counts 15 and 16, while both charging false statements, feature distinct legal theories. There is nothing “unfair” about the government proceeding with one count and not the other.

As to the jury “blaming” Philip because he was president of Stryker Biotech at the time of the April 2007 annual report, any potential “spillover” issue can be cured by limiting instructions. Natanel, 938 F.2d at 308. In any event, much of the evidence concerning Count 15 will be admissible against Philip as a co-conspirator under Count 6.

Like the Sales Defendants, Philip intimates that the joinder of Count 15 might burden his right to testify. (Philip Mot. at ¶12). Like them, Philip has not made a “convincing showing” that he has “important testimony to give concerning [Count 15] and a strong need to refrain from testifying on [the other counts].” Jordan, 112 F.3d 14, 17. He has made no showing at all.

For the reasons stated above, Philip has failed to make a strong and convincing showing that the joinder of Count 15 will unduly prejudice his defense. Accordingly, the government also requests that the Court deny Philip's Rule 14 motion to sever.

CONCLUSION

For all the foregoing reasons, the United States respectfully requests that the Court deny Defendants' motions to sever Count 15.

Respectfully submitted,

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